UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL,

Defendants.

Civ. No. 19-12107 (KM) (ESK)

OPINION

KEVIN MCNULTY, U.S.D.J.:

Plaintiff Zachary Silbersher, as relator, sues Defendants BTG International Ltd. ("BTG"), Johnson & Johnson ("J&J"), and J&J subsidiaries Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC, (collectively, the "J&J Defendants"), for violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and numerous state laws in connection with their acquisition of a patent covering the pharmaceutical drug Zytiga, U.S. Patent No. 8,822,438 ("the '438 Patent"). Now before the Court is

Defendants' motion to dismiss Plaintiff's Second Amended Complaint. (DE 128.)[1] For the following reasons, the motion is **GRANTED IN PART and DENIED IN PART**.

I. BACKGROUND

A. Factual Allegations

The drug Zytiga, the brand-name version of abiraterone acetate, which is used to extend the lives of individuals with metastatic castration-resistant prostate cancer ("mCRPC"), lies at the center of this litigation. (2AC ¶¶ 5, 59; MTD at 2.) Zytiga was developed and is licensed by Defendant BTG but is marketed and sold by J&J and its subsidiaries.[2] (2AC ¶¶ 19-23; MTD at 2.) Zytiga was originally approved by the Food and Drug Administration ("FDA") in April 2011 for use with prednisone, an anti-inflammatory steroid, on chemo-refractory patients (i.e., those who have already undergone chemotherapy). It received further approval in 2012 for chemo-naïve patients (i.e., those with no prior chemotherapy). (2AC ¶ 58; MTD at 2.) J&J previously held the chemical compound patent covering Zytiga, U.S. Patent No. 5,604,213 ("the '213 Patent"), and in 2014, Defendants obtained the patent at issue here, the '438 Patent, which claimed as its proposed invention the co-administration of Zytiga and prednisone at specific dosages to treat prostate cancer.[3] (2AC ¶¶ 8, 22, 25, 60-62, 92-93.) The '213 Patent expired in December 2016, leaving the '438

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[1] Certain citations to the record are abbreviated as follows:

DE refers to the docket entry numbers in this case.

2AC refers to the Second Amended Complaint (DE 63).

MTD refers to Defendants' Brief in Support of its Motion to Dismiss (DE 128).

Ex. C refers to Exhibit C to Defendants' Motion to Dismiss (DE 128).

[2] Defendants state that parsing "which J&J entity did what" in reference to the marketing and sale of Zytiga is "not germane" to the motion, so I address allegations against the J&J Defendants jointly. (MTD at 2 n.4.)

[3] Specifically, J&J, through its subsidiaries, co-owns the '438 Patent with BTG, which was added as co-owner in 2017 pursuant to court order to correct the patent's inventorship. (2AC ¶¶ 25, 91.)

Patent as the sole patent covering Zytiga until January 2018, when it was invalidated. (*Id.* ¶¶ 8, 101-03); *see also BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 383-89 (D.N.J. 2018) (finding the '438 Patent invalid as obvious in light of prior art).

Plaintiff is a patent attorney and co-founder of a patent consulting firm who conducted "independent research and investigation" allegedly showing that Defendants improperly misrepresented Zytiga's commercial success and withheld information from the U.S. Patent and Trademark Office ("PTO") to obtain the '438 Patent, prevent generic competition, and ultimately charge an inflated price for Zytiga to government programs like Medicare and Medicaid. (2AC ¶¶ 8-9, 12, 16-17, 22.)

1. Defendants' Alleged Misrepresentations and Omissions in Applying for the '438 Patent

Defendants began the application process for the '438 Patent in 2011 but faced multiple rejections by the PTO, first in February 2012 when the PTO denied the application, stating that the claimed invention was obvious based on prior art, i.e., that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate in the dosage herein claimed together in a method of treating prostate cancer."[4] (2AC ¶¶ 68-70, 76, 78.) On July 3, 2012, Defendants tried again to show their proposed invention was non-obvious by submitting evidence of Zytiga's commercial success, specifically that within the first year of its release, Zytiga's "worldwide sales were over $400 million."[5] (*Id.*

[4] A claimed invention may not be patented "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103.

[5] A patent applicant may demonstrate that a proposed invention is non-obvious by submitting evidence that the invention was a commercial success as compared with prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 127 S. Ct. 1727, 1734, 167 L. Ed. 2d 705 (2007) (noting that factors such as "commercial success, long felt but unsolved needs, [and] failure of others" can be used to determine whether a

¶ 77.) The Patent Office again rejected Defendants' application as obvious in September 2012, finding that Defendants' evidence of commercial success was unpersuasive because "gross sales figures do not show commercial success absent evidence as to market share, or as to the time period during which the product was sold, or as to what sales would normally be expected in the market." (*Id.* ¶¶ 75-81 (citations omitted).)

In order to supplement their evidence of commercial success and overcome the PTO's concerns, Defendants submitted additional application materials on June 4, 2013, representing that Zytiga had increased its market share between December 2012 and April 2013. (*Id.* ¶ 82.) Specifically, they claimed that Zytiga's market share of the "submarket" of chemo-naïve mCRPC patients had increased from fifteen to twenty percent, representing a three percent increase in Zytiga's market share in the mCRPC market overall. (*Id.* ¶¶ 82-83.) Defendants claimed that this new market share was higher than that of two other therapies for prostate cancer, docetaxel and Xtandi, and was "approaching" the market share of a third drug, bicalutamide. (*Id.* ¶ 82.)

It is these representations of Zytiga's increase in market share that Plaintiff alleges are "misleading and fraudulent," and therefore violative of Defendants' duty of candor and good faith to the PTO.[6] (*Id.* ¶¶ 42, 58, 63-65, 84.) First, Plaintiff cites Defendants' comparison of Zytiga with Xtandi in the chemo-naïve mCRPC submarket from December 2012 to April 2013 as a knowing and intentional attempt to mislead the PTO. Xtandi, says Plaintiff, was

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patent's subject matter is obvious or not under 35 U.S.C. § 103 (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)).

[6] Federal regulation provides that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO]," including a duty to disclose "all information known to that individual to be material to patentability." 37 C.F.R. § 1.56(a). Individuals bound to the duty of candor and good faith include (1) "[e]ach inventor named in the application"; (2) "[e]ach attorney or agent who prepares or prosecutes the application"; and (3) "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application." *Id.* § 1.56((c).

not approved for chemo-naïve patients until September 2014, and within 16 months of its approval, it had overtaken Zytiga in market share for both chemo-naïve and mCRPC patients overall.[7] (*Id.* ¶ 84(a)-(d).) Second, Plaintiff alleges that Defendants improperly based their market share data on Zytiga's patient market share, rather than its direct sales market share compared with other drugs.[8] (*Id.* ¶ 84(e).) Finally, Plaintiff claims that Defendants' comparison of Zytiga to the drug bicalutamide was misleading because bicalutamide, an older drug used for patients with prostate cancer, did not "materially increase[e] survivability" and so by 2012, it was "increasingly being prescribed for specific purposes in conjunction with treatment that was considered to be more efficacious." (*Id.* ¶ 84(f).)

Following these representations, the PTO issued a Notice of Allowance, leading to the eventual issuance of the '438 Patent on September 2, 2014. (*Id.* ¶¶ 25, 85.) Given the PTO's earlier rejections and its focus on evidence concerning Zytiga's market share, Plaintiff alleges that "the single most reasonable explanation for the Patent Office's approval of the '438 Patent was Defendants' fraudulent and misleading statements concerning Zytiga's growth in the chemo-naïve mCRPC market." (*Id.* ¶ 86.)

Plaintiff also alleges that Defendants failed to disclose that Zytiga's purported commercial success lacked the requisite nexus to the invention that Defendants claimed, i.e., the co-administration of abiraterone acetate with

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[7] Plaintiff cites, as evidence that Defendants knew these statements were false or misleading, Defendants' representation that Zytiga's market share in the chemo refractory mCRPC market had dropped from 70% in July 2012 to 57% in April 2013, which Defendants explained as a result of the FDA's approval of Xtandi for the chemo-refractory market in August 2012. (2AC ¶ 84(b)-(c).) Moreover, to Plaintiff, Defendants' decision to report market share data starting in December 2012 for the chemo-naïve mCRPC market but in July 2012 for the chemo-refractory mCRPC market "demonstrates that Defendants knew that the date of FDA approval was a material consideration" yet withheld the relevant approval dates for Xtandi. (*Id.* ¶ 84(d).)

[8] Indeed, because individuals suffering from prostate cancer "often take many drugs," market share calculations based on patient, rather than direct sales, can result in a total market share exceeding one hundred percent. (2AC ¶ 84(e).)

prednisone. Rather, Plaintiff alleges, its success was due to (1) its novelty and the frequency that mCRPC patients switch medications; (2) being launched before Xtandi in the chemo-refractory mCRPC market; (3) new urology treatment guidelines that, in some cases, recommended Zytiga as the least toxic of relevant medications; (4) the prior '213 Patent's effect of blocking competition from any generic drug manufacturers; (5) Zytiga not being prescribed to alleviate side effects of prostate cancer, as Defendants represented; (6) Zytiga being between thirty and fifty percent cheaper than competitors Xtandi and Jevtana; and (7) sales of Zytiga that were not used for coadministration with prednisone—the '438 Patent's claimed invention. (*Id.* ¶ 87(b)-(f), (h)-(i).) Plaintiff finally alleges that Defendants made other misleading statements to the Patent Office to secure the '438 Patent, including (1) that Zytiga was "the most successful oral oncology launch in history" and (2) that Zytiga, an oral medication, had greater success than the medication Jevtana without disclosing that Jevtana was administered intravenously. (*Id.* ¶ 87(a), (g).)

2. Invalidation of the '438 Patent

In January 2018, the Patent Trial and Appeal Board ("PTAB") invalidated the '438 Patent in multiple inter partes review actions brought by several generic drug manufacturers. (2AC ¶ 101 (citing *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms., Inc. v. Janssen Oncology, Inc.*, IPR2016-01332 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio AG v. Janssen Oncology, Inc.*, IPR2016-01582 (P.T.A.B. Jan. 17, 2018)).) PTAB denied Defendants' request for rehearing and Defendants appealed to the Federal Circuit. (*Id.* ¶ 101.) On October 31, 2018, I issued an opinion in *BTG Int'l Ltd. v. Amneal Pharm. LLC* in which I determined that the '438 Patent was invalid as obvious in light of prior art, a decision which Defendants also appealed to the Federal Circuit. (*Id.* ¶ 102 (citing 352 F. Supp. 3d 352 (D.N.J. 2018)). The Federal Circuit ultimately affirmed both

decisions in a consolidated opinion on May 14, 2019. (*Id.* ¶ 102 (citing *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019)).

3. Defendants' Alleged Use of '438 Patent to Block Competition

The approved '438 Patent was published in an FDA database called "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."[9] (2AC ¶¶ 42-43, 58, 92.) For a company to obtain approval of a generic equivalent to an FDA-approved, patented, brand-name drug listed in the Orange Book, it must submit a certification that the patent for the brand-name drug is invalid or will not be infringed by a proposed generic product – a "Paragraph IV certification." (*Id.* ¶¶ 48-50.) The filing of a Paragraph IV certification permits brand manufacturers to "trigger extensive regulatory delays" to block FDA approval of a generic product, including the initiation of a patent infringement action. (*Id.* ¶¶ 48-51.) In response to such actions, the FDA will withhold final approval for a generic version until the infringement action has been resolved or a period of 30 months has elapsed. (*Id.* ¶ 51.)

Accordingly, Plaintiff alleges that the '438 Patent's publication in the Orange Book allowed Defendants to delay generic entry into the market and to earn "over $2.5 billion in Zytiga sales at supracompetitive prices" while such generics were excluded.[10] (*Id.* ¶¶ 58, 93-96.) Specifically, Plaintiff claims that numerous generic drug manufacturers had applied for approval of generic versions of Zytiga and that "over a dozen" of them would have been able to gain such approval by December 13, 2016, when the '213 Patent expired, but for the listing of '438 Patent in the Orange Book. (*Id.* ¶ 58, 94-96.) The listing of

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[9] Patents are published in the Orange Book in connection with the FDA's approval of a drug pursuant to a New Drug Application ("NDA"). (2AC ¶ 42) The '438 Patent was published in the Orange Book in connection with the J&J Defendants' preexisting NDA for Zytiga. (*See id.* ¶¶ 24, 26, 42 (citing 21 U.S.C. § 355(c)(2)).)

[10] Though Plaintiff does not detail how he arrived at this figure of "over $2.5 billion," it appears to be based on estimated Zytiga sales of "over $1 billion" in the U.S. annually multiplied by the 30-month stay of FDA approval. (*See* 2AC ¶¶ 6, 9, 58, 132.)

the '438 Patent instead forced these generic manufacturers to file Paragraph IV certifications, allowing Defendants to file patent infringement lawsuits that Plaintiff characterizes as "sham litigation" and to trigger a 30-month stay of FDA approval of the generics.[11] (*Id.* ¶ 98-99, 105.)

Plaintiff alleges that of the $2.5 billion that Defendants allegedly earned during this 30-month period, a "significant portion" of it came from "government funds through Medicare, Medicaid, and other programs."[12] (*Id.* ¶ 58.) Plaintiff claims that Defendants independently defrauded the government by representing to governmental authorities that they were charging a "fair and reasonable" price for Zytiga, specifically through (1) listing Zytiga's price on the General Service Administration's ("GSA") Federal Supply Schedule; (2) participation in the Department of Health and Human Service's ("HHS") Medicaid Drug Rebate program; and (3) participation in HHS's Section 340B Drug Pricing Program. (*Id.* ¶ 7, 110-17.) All three programs required Defendants to submit Zytiga's product and pricing information to relevant agencies. (*Ibid.*) Yet Plaintiff maintains that Zytiga's price was inflated by the monopoly that the '438 Patent provided, allowing Defendants to overcharge government programs that bought Zytiga or reimbursed Defendants for it. (*Id.* ¶¶ 117-19.) Indeed, he notes that entry of generic drugs into a pharmaceutical market can lower prices of a given pharmaceutical by as much as eighty five percent and can capture as much as ninety percent of the market. (*Id.* ¶¶ 55,

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[11] Plaintiff lists a total of 16 pharmaceutical companies that had applied for FDA approval of a generic version of Zytiga and cites two that eventually received approval in October 2017 although both could have supplied "commercial quantities of generic Zytiga" as of at least December 2016. (2AC ¶ 94, 100.)

[12] Plaintiff characterizes the fraction of the $2.5 billion originating from the government fisc as a "large majority," noting that (1) Medicare covers approximately 80% of prostate cancer patients; (2) the federal government additionally buys Zytiga through programs such as the Veterans Health Administration, the Indian Health Service, and the Federal Bureau of Prisons' Health Services Division, among others; and (3) state Medicaid programs also cover Zytiga. (2AC ¶ 6.) Additionally, he cites the Department of Heath and Human Services estimate that in 2017, Medicare Part D and Medicaid payments for Zytiga totaled approximately $877,587,632.97. (*Id.* ¶ 7.)

124.) Unsurprisingly, then, "[m]any government programs require patients to use or consider using generic alternatives before using more expensive name-brand drugs," and the exclusion of generic manufacturers from the market can prove "especially damaging to the government." (*Id.* ¶ 109.)

B. Procedural History

Plaintiff filed the operative Second Amended Complaint on June 20, 2019, alleging that Defendants violated the federal FCA. The Second Amended Complaint also asserts that Defendants violated numerous state laws that are characterized as the FCA's "state counterparts"—thirty claims under the laws of twenty-seven different states and the District of Columbia in all.[13] (DE 63; 2AC ¶¶ 1, 147-496.)

On April 6, 2021, Defendants filed a motion to dismiss the Second Amended Complaint, arguing that all of Plaintiff's claims must be dismissed because they (1) rely on publicly available information; (2) fail to state an FCA claim's essential elements, particularly falsity and materiality; and (3) fail to allege underlying fraud with sufficient particularity. (DE 128.) Additionally, Defendants argue that Plaintiff's claims against Defendant BTG must be dismissed because the complaint fails to state with sufficient particularity that BTG knowingly participated in fraud or conduct barred by the FCA. (*Ibid.*)

II. DISCUSSION AND ANALYSIS

A. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), the Court may dismiss a complaint, in whole or in part, if the plaintiff fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). On such a motion, the well-pleaded factual allegations of the complaint must be taken as

13 These state-law claims are predicated on Plaintiff's allegation that the inflated price of Zytiga also caused extra costs for state government programs because Medicaid is jointly administered between the states and federal government, each providing funds to reimburse prescription drug providers. (2AC ¶¶ 38-40.)

true, with all reasonable inferences drawn in plaintiff's favor. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008).

Although a complaint need not contain detailed factual allegations, "a plaintiff's obligation to provide the 'grounds' of [his] 'entitlement to relief requires more than labels and conclusions." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also* Fed. R. Civ. P. 8(a)(2) (requiring a complaint to plead "a short and plain statement of the claim showing that the pleader is entitled to relief"). Thus, the factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, demonstrating that it is "plausible on its face." *See Twombly*, 550 U.S. at 570; *see also Umland v. PLANCO Fin. Servs.*, Inc., 542 F.3d 59, 64 (3d Cir.2008). This entails "plead[ing] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Id.* at 678. Stated differently, in reviewing the well-pleaded factual allegations and assuming their veracity, this Court must "determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679.

Further, for claims sounding in fraud, Fed. R. Civ. P. 9(b) imposes a heightened pleading requirement, over and above that of Rule 8(a): "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Rule 9(b) thus requires a complaint to state the circumstances of an alleged fraud with "sufficient particularity to place the defendant on notice of the precise misconduct with which [it is] charged." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (internal quotation marks omitted).

B. False Claims Act

The FCA imposes liability on any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of subparagraph (A) [or] (B),
>
> 31 U.S.C. § 3729(a)(1)

A private plaintiff (or relator) may bring a civil action on behalf of the United States to enforce the FCA and may receive a share of any recovery resulting from the lawsuit. 31 U.S.C. § 3730(b), (d); *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pennsylvania*, 728 F. App'x 101, 102 n.2 (3d Cir. 2018). To state a cause of action under the FCA, a plaintiff must allege "four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016) and *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304-05 (3d Cir. 2011)).

In the context of an FCA claim, Rule 9(b) requires that a relator's allegations of fraud must be supported "with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Securities Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)); *see United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 272 (3d Cir. 2016). However, the Third Circuit has clarified that under this pleading standard, a plaintiff need not identify a specific claim for payment. *Foglia v. Renal Ventures Mgmt.*, LLC, 754 F.3d 153, 156 (3d Cir. 2014). "[I]t is sufficient for a plaintiff to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* at 156-57 (quoting *United States ex rel Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)); *see also United States ex Rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011) (stating that a plaintiff, at the

pleading stage, is not required to "identify a specific claim for payment . . . to state a claim for relief.").

"It is certainly true that allegations of 'date, place or time' fulfill these functions, but nothing in the rule requires them. Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984); *United States ex rel. Judd v. Quest Diagnostics Inc.*, 638 F. App'x 162, 168-69 (3d Cir. 2015) (finding that to satisfy Rule 9(b)'s requirement to allege "the who, what, when, where and how of the events" giving rise to an FCA claim, a plaintiff must allege the particular details of a scheme). However, "[d]]escribing a mere opportunity for fraud will not suffice." *United States v. Omnicare, Inc.*, 903 F.3d 78, 91 (3d Cir. 2018) (quoting *Foglia*, 754 F.3d at 158).

i. FCA's Public Disclosure Bar

The FCA's public disclosure bar limits the information that a relator can use to pursue a qui tam action in order to "strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits," such as those based solely on evidence of which the Government already has notice. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 293-95 (2010). The public disclosure bar requires a court to dismiss an FCA action or claim "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in one of three enumerated sources: (i) "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party" ("channel (i)"); (ii) "a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation" ("channel (ii)"); or (iii) "news media" ("channel (iii)") 31 U.S.C. § 3730(e)(4)(A)(i)-(iii). Congress amended the FCA in 2010 and in so doing "overhauled the public disclosure bar," "radically chang[ing] the 'hurdle' for relators." *Moore*, 812 F.3d at 298. Most relevant here, Congress added to channel (i) the specifications that the hearings at issue must be

federal and that they must have the Government as a party, meaning that information "disclosed in a federal case between private parties no longer constitutes publicly disclosed information" under the FCA. *Ibid.* "Although no direct legislative history seems to exist" for the FCA's 2010 amendments, "the textual changes alone evince Congress's intent to lower the bar for relators, at least as to some of its components." *Id.* at 299.

Defendants argue that Plaintiff's FCA claim must be dismissed pursuant to the public disclosure bar because (1) substantially the same allegations were publicly disclosed in the inter partes review ("IPR") petitions that led to the '438 patent's invalidation; and (2) substantially the same transactions underlying the claim, i.e. Defendants' alleged misrepresentations and omissions, were disclosed in Defendants' submissions to the PTO and in articles and websites concerning science and medicine. (MTD at 7-23.) In assessing Defendants' argument, I look first to "whether the sources on which [they] rely in arguing that the alleged fraud was publicly disclosed qualify as public disclosure sources" before turning to whether "substantially the same allegations or transactions" of fraud were publicly disclosed through qualifying sources, if any. *Id.* at 301.

First, I turn to Defendant's argument—a concededly "novel" one—that IPR proceedings constitute a "hearing" under either channel (i) or channel (ii). (MTD at 17-19.) Channel (i), however, is limited to hearings to which the Government is a party; the Government is not a party to the IPR process. Rather, IPR is a proceeding between a petitioner and patentholder, and is closely akin to a private civil litigation. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) (noting that "the inter partes review regime looks a good deal" like civil litigation and bears many of a civil suit's "usual trappings," such as briefing, discovery, and opportunity for private settlement); *see also, e.g.*, 35 U.S.C. §§ 312-13 (governing IPR petitions and preliminary responses); 35 U.S.C. § 316 (requiring the establishment of regulations for conducting IPR proceedings, including for discovery, sanctions, and oral hearings); 35 U.S.C. §

317 (governing IPR settlement). Still, Defendant justifiably points to the Government's "substantive role" in IPR proceedings; the PTO Director will only institute IPR proceedings where a petitioner "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition," 35 U.S.C. § 314(a), and PTAB may render a final written decision even if the petitioner stops participating, *see* 35 U.S.C. § 317(a). These powers indeed suggest that the purpose of the IPR regime "is not quite the same as the purpose of district court litigation" and highlight that IPR proceedings are in significant respects "more like a specialized agency proceeding." *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279 (2016). Nonetheless, the powers exercised by the PTO do not place it on the same footing as the petitioner and patentholder who are the actual parties to the IPR proceeding, and the PTO does not thereby take on the status of a government "party" to that proceeding. *See id.* at 278-79 (referring to an IPR proceeding's "parties" as petitioner and patentholder); *Iancu*, 138 S. Ct. at 1253-54 (same); *see also* "Party," *Black's Law Dictionary* (11th ed. 2019) (defining "party" as "[o]ne by or against whom a lawsuit is brought; anyone who both is directly interested in a lawsuit and has a right to control the proceedings, make a defense, or appeal from an adverse judgment.")

I therefore am not persuaded by Defendants' argument that such IPR proceedings constitute a "Federal hearing" within the meaning of channel (ii). Nor am I persuaded that the Defendant's position is supported by the cited authorities. Defendants cite another case involving this Plaintiff, *Silbersher v. Valeant Pharms. Int'l, Inc.*, in which the District Court for the Northern District of California found that information disclosed in litigation before PTAB qualified as a public disclosure in a federal hearing under channel (ii). 445 F. Supp. 3d 393, 405-06 (N.D. Cal. 2020) (finding that PTAB's adjudicative function in conducting IPR trials "falls squarely within the plain meaning of a federal hearing as used in Section 3730(e)(4)(A)(ii)"). I respectfully part ways, however, with the decision in *Valeant* and find that categorizing IPR proceedings as

federal hearings under channel (ii) would undermine the purpose of limiting channel (i) to federal hearings to which the Government is a party—it would draw those hearings specifically excluded from channel (i) back into the public disclosure bar under the guise of channel (ii). *See Silbersher v. Allergan Inc.*, 506 F. Supp. 3d 772, 807 (N.D. Cal. 2020) (noting that *Valeant*'s "reading of the term 'Federal . . . hearing' appears to be in direct conflict with what Congress intended when it amended the public disclosure bar in 2010"). Congress's 2010 amendments were intended to narrow the definition of publicly disclosed information, not merely to shift the definition from one channel to another, or to spread the same definition between two subsections. While the FCA may "contemplate some redundancy," *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 410 (2011), I cannot interpret it in a way that would negate evident Congressional intent, *see Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018) ("[T]he Court is 'obliged to give effect, if possible, to every word Congress used.'" (quoting *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979)). I hold that IPR proceedings do not fall within the FCA's three enumerated channels of public disclosure.

Alternatively, Defendants urge that the patent prosecution materials on which Plaintiff relies have been publicly disclosed in a "Federal report" under channel (ii) because they were "published" on the PTO's Patent Application Information Retrieval ("PAIR") system.[14] (MTD at 19.) Yet this argument also

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[14] The PTO is required to publish patent applications on PAIR "promptly" once 18 months have elapsed since "the earliest filing date for which a benefit is sought." 35 U.S.C. § 122; 37 C.F.R. §1.211. The Patent Office's Manual of Patent Examining Procedure explains that:

> [t]here is both a public and private side to PAIR. In public PAIR, information is available relating to issued patents, published patent applications, and applications to which a patented or published application claims domestic priority. In private PAIR, an applicant (or his or her registered patent attorney or registered patent agent) can securely track the progress of his or her application(s) through the [Patent Office]. Private PAIR makes available information relating to unpublished patent applications, but the applicant must associate a Customer Number with the application to obtain access.

devalues the evident intent behind Congress's 2010 amendment to channel (i). Patent prosecutions are ex parte administrative proceedings to which the Government is not a party and, as such, would evidently be excluded from the post-2010 version of channel (i). Yet by recharacterizing these materials as public because contained within a Federal report, Defendants' argument would "eviscerate[]" Congress's limitation of channel (i), rendering "any federal proceeding with a public docket—regardless of whether or not the Government was a party— . . . a permissible channel that could trigger the public disclosure bar." *Allergan Inc.*, 506 F. Supp. 3d at 800; *see also Schindler*, 563 U.S. at 408 ("[T]o determine the meaning of one word in the public disclosure bar, we must consider the provision's 'entire text,' read as an 'integrated whole'" (quoting *Graham*, 559 U.S. at 290, 293)). Indeed, this argument might be extended to encompass, for example, every civil case published on the PACER electronic docket, sweeping materials obviously excluded from channel (i) back in under channel (ii). *See Allergan Inc.*, 506 F. Supp. 3d at 802; *see also Moore*, 812 F.3d at 299 (noting that under the 2010 amendments to the FCA, information disclosed in a private civil suit "no longer constitutes publicly disclosed information"). In short, Defendants' interpretation of the public disclosure bar would make channel (i) superfluous and ignore Congress's evident intent in amending it. I therefore cannot agree that Plaintiff's claims were publicly disclosed, for purposes of channel (ii), by virtue of their appearance in the PAIR system. *See Nat'l Ass'n of Mfrs.*, 138 S. Ct. 617, 632 (2018) ("Absent clear evidence that Congress intended this surplusage, the Court rejects an interpretation of the statute that would render an entire subparagraph meaningless.").

Finally, Defendants argue that Plaintiff's allegations have been publicly disclosed for purposes of channel (iii) because they have appeared in the news

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Manual of Patent Examining Procedure § 1730(II)(B)(1)(c). Defendants allege, and Plaintiff does not contest, that documents relevant to Defendants' application for the '438 Patent were publicly viewable on PAIR after June 16, 2011. (MTD at 20 n.29.)

media. In Defendants' view, a variety of online and print sources qualify as news media because they are "curated" and bear "indicia of reliability" akin to those of traditional news sources. *See Graham*, 559 U.S. at 290 (noting that "news media" in channel (iii) "likely describes a multitude of sources that would seldom come to the attention of the Attorney General"); *see also, e.g., U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (holding that, under channel (iii), both newspaper advertisements and publicly available websites qualify as "news media"); *U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y.) (finding that "scholarly or scientific periodicals" qualify as "news media" because their "authors also disseminate information to the public in a periodic manner," just like newspaper reporters). Grant *arguendo* Defendants' broad definition of "news media," and grant that some portion of the Plaintiff's allegations appeared therein. I nevertheless find that Defendants have failed to allege that the true substance of the Plaintiff's allegations was publicly disclosed. *See Moore*, 812 F.3d at 303 (noting that, to invoke the public disclosure bar, a defendant must show that "substantially the same" allegation or transaction of fraud was disclosed through channels (i)-(iii)); *see also, e.g., United States ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 235–36 (3d Cir. 2013) ("A transaction warranting an inference of fraud is one that is composed of a misrepresented state of facts plus the actual state of facts.").

As outlined above, Plaintiff's myriad allegations center on the claim that Defendants misrepresented Zytiga's commercial success to the PTO by comparing it misleadingly to the drugs Xtandi and bicalutamide, allowing Defendants to wrongfully procure the '438 Patent and forestall generic competition. The sources that Defendants cite contain information that is concededly relevant to the instant dispute—such as pharmaceutical details (e.g. Zytiga's ability to prolong survival and Xtandi's FDA approval dates) and scientific or medical context (e.g. patterns in mCRPC drug usage by cancer patients)—but this information, standing alone, does not reveal the substance

of Plaintiff's allegations. I therefore will not dismiss Plaintiff's complaint pursuant to the FCA's public disclosure bar on the basis of channel (iii).[15]

ii. Sufficiency of Plaintiff's Allegations

Setting aside the public disclosure bar, Defendants argue that Plaintiff's FCA claim should be dismissed pursuant to Rule 12(b)(6) because it fails to plead the elements of falsity and materiality and fails to allege fraud with the specificity required by Rule 9(b).[16] As detailed below, I find that Defendants have failed to demonstrate that no claim has been stated and thus I deny their motion to dismiss as to the J&J Defendants. As to Defendant BTG, I address Defendants' arguments separately in Section II.C.

a. Falsity

Falsity under the FCA may be either factual or legal. *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). A claim of factual falsity, as opposed to legal falsity, requires an allegation that the claimant misrepresented the goods or services that it provided to the Government. *Wilkins*, 659 F.3d at 305. No claim of factual falsity is made here. Legal falsity imports that a defendant knowingly and falsely certified that it had "complied with a statute or regulation, the compliance with which is a condition for Government payment." *Ibid.* As to legal falsity, there are two subsidiary

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[15] Even if the allegations were disclosed in enumerated channels, Plaintiff argues, the public disclosure bar would not apply because Plaintiff qualifies as an "original source," i.e., "an individual who either [1] prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B). Having concluded that Plaintiff's allegations were not publicly disclosed in the FCA's enumerated channels, I do not reach this issue.

[16] Defendants urge that Plaintiff's failure to plead falsity and materiality extends to Plaintiff's claims under state law and requires their dismissal as well. (MTD at 24 n.31.) Because Defendants offer no independent reason to dismiss these claims, I will proceed with the parties' apparent assumption that Plaintiff's FCA claim and his state law claims rise and fall together for the purpose of this motion.

theories: express false certification and implied false certification. "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Ibid.* (citation omitted). Under the "implied false certification" theory, an entity is liable if it "seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Ibid.*; *see also Escobar*, 579 U.S. at 193) (holding that liability may be imposed under an implied certification theory where the claim "makes a specific representation about the good or services provided" and the defendant's "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths").

Apart from the main categories of factually and legally false claims, the law has recognized "a narrow, third category of false claims obtained by 'fraud-in-the-inducement.'" *In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig.*, 332 F. Supp. 3d 927, 939 (D.N.J. 2017). Courts have employed this theory to establish FCA liability "for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014). To establish an FCA violation under this theory, "a plaintiff must show that (1) there was a knowingly false or fraudulent statement; (2) that the statement was material; and (3) that it caused the government to pay out money or to forfeit moneys due (i.e., a "claim")." *Ibid.*

Here, Plaintiff relies on false certification and fraudulent inducement to allege three theories of Defendants' liability and meet the FCA's falsity requirement: (1) Defendant's misrepresentations to the PTO to obtain the '438 Patent; (2) Defendant's misrepresentations to the PTO which "tainted subsequent claims for payment" for Zytiga from government programs; and (3) Defendant's misrepresentation to government agencies that Zytiga's price was

"fair and reasonable." I find that Plaintiff has sufficiently pleaded falsity, and therefore his FCA claim (along with his corresponding state-law claims) can proceed beyond the threshold of a motion to dismiss on that issue.

First, Plaintiff has plausibly alleged that Defendants' representations to PTO in order to obtain the '438 Patent were false or misleading. The complaint alleges that Defendants (1) misleadingly compared Zytiga's success to Xtandi in the chemo-naïve mCRPC submarket from December 2012 to April 2013, even though Xtandi would not be approved for that submarket until over a year later; (2) misleadingly calculated Zytiga's market share data based on Zytiga's patient market share, rather than its direct sales market share; and (3) misleadingly compared Zytiga to bicalumatide even though that drug's use was more circumscribed. (2AC ¶ 84(a)-(f); MTD Ex. C.) These statements, alleged to be at odds with known facts about Zytiga and its competitors, are all specific allegations of fraud that sit at odds with a patent applicant's duty of candor to the Patent Office. Allegedly, the motivation for such representations was to secure eligibility for the patent. *See Escobar*, 579 U.S. at 193; *see also* 31 U.S.C. § 3729(b)(2)(A) (defining a claim as "any request or demand, whether under a contract or otherwise, for money or property"); *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1375 (2018) (noting that patents are "entitled to protection as any other property" and, subject to the Patent Act's provisions, "shall have the attributes of personal property" (quoting first *Seymour v. Osborne*, 78 U.S. 516, 533 (1870), then 35 U.S.C. § 261)). These allegations suffice to meet the FCA's falsity requirement.

To complete the picture, I consider from a different analytic perspective the allegations that misrepresentations to the Patent Office "tainted subsequent claims for payment" for Zytiga and that misrepresentations to government agencies wrongfully portrayed Zytiga's price as "fair and reasonable." These I discuss together, as they bear on the same, allegedly fraudulent, transaction. The theory that Defendants fraudulently obtained a patent on Zytiga so they could charge an inflated price to government programs may alternatively be viewed as one under implied false certification or one under fraudulent

inducement. Under the former, Plaintiff has sufficiently alleged that Defendants made "specific representation[s]" about Zytiga, *see Escobar*, 579 U.S. at 193, namely, telling government agencies such as GSA and HHS that Zytiga's price was fair and reasonable. (*See* 2AC ¶¶ 106-19.) Moreover, Plaintiff has alleged that Defendants' failure to provide truthful information to PTO regarding Zytiga's commercial success or to otherwise disclose its prior dishonesty rendered representations about the fairness or reasonableness of its price "misleading half-truths." *See Escobar*, 579 U.S. at 193. Under a fraudulent inducement theory, Plaintiff alleges that (1) Defendants' statements to government agencies regarding Zytiga's price and commercial success were "knowingly false or fraudulent"; (2) these statements were material to the Government's decision to approve the '438 Patent and qualify Defendants for participation in programs such as GSA's Federal Supply Schedule and the Medicaid Drug Rebate Program; and (3) the government ultimately paid Defendants pursuant to these programs. *See Thomas*, 593 F. App'x at 143.

In sum, Plaintiff has pleaded falsity sufficiently for his complaint to survive a motion to dismiss.

b. Materiality

Defendants also argue that Plaintiff has failed to sufficiently plead materiality under the FCA. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *see also Escobar*, 579 U.S. at 193 (explaining that a statement is material under the FCA where a reasonable person would "attach importance to [it] in determining his choice of action" or where the defendant knows that a person attaches importance to such a statement in determining choice of action, whether reasonable or not). "[W]hen evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Escobar*, 579 U.S. at 194.

Here, Plaintiff alleges materiality in sufficient detail at two different, critical points in his description of a multi-step, years-long fraud. First, he claims that Defendants' representations to the PTO regarding Zytiga's commercial success followed repeated rejections and a specific request for market share information by the PTO. It was only after Defendants allegedly misrepresented Zytiga's success that the PTO approved the application for the '438 Patent. Such a showing is sufficient to demonstrate that Defendants' alleged misrepresentations to the PTO were material and, indeed, tipped the scales of Zytiga's patent prosecution in Defendants' favor. Second, Plaintiff claims that Defendants represented to both GSA and HHS that Zytiga's price was fair and reasonable, i.e., not a product of manipulating the patent system, as both statute and regulation require that they do. *See, e.g.*, 38 U.S.C. § 8126(a); 42 U.S.C. § 1396r-8(b)(3)(C)(ii); 42 C.F.R. § 414.804(a)(5); 48 C.F.R. 15.405(a)-(b). Representing that the price of Zytiga is fair and reasonable was mandated as part of Defendants' participation in GSA's Federal Supply Schedule, HHS's Medicaid Drug Rebate Program, and HHS's Section 340B Drug Pricing Program, all of which Defendant allegedly used to sell Zytiga directly to government agencies or to receive reimbursement for Zytiga sales from Medicaid. (*See* 2AC ¶¶ 106-19.) While this requirement is not itself "dispositive," it touches upon an essential characteristic of Zytiga for government procurement purposes, namely, its price. (*See* 2AC ¶¶ 55, 124 (noting that the entry of generic drugs into a pharmaceutical market can lower drug prices by as much as 85 percent)).

I conclude that Plaintiff has properly pleaded materiality, alleging that Defendants' misrepresentations to the PTO and other government agencies had a natural tendency or capacity to influence government decisions to approve Defendants' patent application and pay inflated prices for Zytiga.

c. Adequacy of pleading fraud

Defendants argue that Plaintiff's complaint fails to plausibly allege fraud under Rule 9(b) and characterizes the fraud's basis—Defendant's alleged

breach of their duty of candor to the PTO—as "predicated on inequitable conduct" and therefore defined by Federal Circuit precedent. (MTD at 35-36 (citing *Ragner Tech. Corp. v. Berardi*, 324 F. Supp. 3d 491, 506 (D.N.J. 2018) (applying Federal Circuit law to determine if a patent was obtained through actual fraud upon the PTO for purposes of a *Walker Process* anti-trust claim))). Based on this precedent, Defendants maintain that the complaint (1) fails to connect alleged violations of the duty of candor by individuals to the Defendant corporations; (2) fails to allege a specific intent to deceive; and (3) fails to show the alleged misrepresentations and omissions to the PTO were material to, and the but-for cause of, the PTO's eventual issuance of the patent. (MTD 36-38.)

I cannot find justification for Defendants' attempt to shoehorn antitrust caselaw from the Federal Circuit into this case. Plaintiff's complaint involves a different statute, subject matter, and circuit. "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). In comparison, a *Walker Process* anti-trust claim provides "proof that a patentee has 'obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office'" in order "to strip [the patentee] of its exemption from the antitrust laws." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007) (quoting *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965)). These doctrines are judicially-crafted and designed for different statutory contexts than the FCA; their roots lie in the antitrust statute and the equitable doctrine of unclean hands, *see Therasense*, 649 F.3d at 1285; *Walker Process*, 382 U.S. 175-77, while an FCA claim's elements are derived in part from common-law fraud and in part from the FCA's text, see *Escobar*, 579 U.S. at 187 n.2, 187-88, 193).[17] I therefore will not

[17] Moreover, although Defendants argue otherwise, the FCA's scienter requirement "require[s] no proof of specific intent to defraud." *Escobar*, 579 U.S. at 187 n.2 (quoting 31 U.S.C. § 3729(b)(1)(B)).

accept Defendants' suggestion to displace either the FCA's plain text or the Third Circuit's surrounding jurisprudence.

That foundation laid, I find that Plaintiff's allegations of fraud under the FCA meet the pleading requirements of Rule 9(b), at least as to the J&J Defendants. While this case is perhaps a close one, Plaintiff has provided the "who, what, when, where and how of the events at issue," *Moore*, 812 F.3d at 307 (quoting *Rockefeller*, 311 F.3d at 217). As outlined above, Plaintiff alleges that the J&J Defendants, in applying for the '438 Patent, made a series of misrepresentations and omissions to PTO designed at demonstrating Zytiga's commercial success, including: (1) comparing Zytiga's success to Xtandi in the chemo-naïve mCRPC submarket; (2) calculating Zytiga's market share data on Zytiga's patient market share; and (3) comparing Zytiga to bicalumatide.[18] (2AC ¶ 84(a)-(f); MTD Ex. C.) These representations and omissions followed repeated rejections of Defendants' application for the '438 Patent and PTO's express concern that it receive information regarding Zytiga's market share. (2AC ¶¶ 68-82.) The '438 Patent was issued, following the J&J Defendants alleged misrepresentations and omissions, on September 2, 2014, and was the sole patent covering Zytiga from December 2016, when the '213 Patent expired, until January 2018, when the '438 Patent was invalidated. (2AC ¶¶ 8, 25, 85, 101-03.) Finally, Plaintiff alleges that the J&J Defendants' monopoly on Zytiga allowed them to maintain much higher prices for Zytiga by excluding generic competitors during a time period when the Government spent millions of dollars on Zytiga. (*See, e.g.*, *id.* ¶ 7 (noting that Medicare Part D and Medicaid payments for Zytiga totaled approximately $877,587,632.97 in 2017)). While these allegations do not cite "a specific claim for payment," they nonetheless provide "particular details of a scheme to submit false claims paired with

[18] Plaintiff alleges that Defendants made a number of other misrepresentations and omissions to PTO regarding Zytiga's commercial success, (*see* 2AC ¶ 87), but does not assign them the same importance in PTO's decision-making as the above allegations, (*see id.* ¶ 84-86.)

reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia*, 754 F.3d at 156-57 (quoting *Grubbs*, 565 F.3d at 190).

Accordingly, the J&J Defendants have failed to demonstrate that Plaintiff's FCA claim warrants dismissal.

C. Plaintiff's Claims Against Defendant BTG

Defendants argue that Defendant BTG is not a proper party to this case because (1) BTG did not prosecute the '438 patent and therefore cannot be alleged to have had knowledge of the alleged fraud; and (2) the complaint lacks "any particularized allegations" that BTG knowingly violated the FCA. Indeed, Plaintiff's complaint says little about BTG beyond its co-ownership of the '438 Patent and its participation in at least three civil infringement actions against generic competitors. (2AC ¶¶ 25, 91, 102 n.2.) With so little detail offered about BTG's conduct, I cannot conclude that Plaintiff has properly pleaded that BTG knew of the alleged fraud, at least at the level of specificity contemplated by Rule 9(b). As Defendants note, Plaintiff alleges that BTG only became the '438 Patent's co-owner after it was issued, making the claim that BTG knew of or participated in the other Defendants' misrepresentations in obtaining that patent speculative at best. Indeed, even taking for granted Plaintiff's assertion that BTG and the other Defendants independently told government agencies that Zytiga's price was fair and reasonable, (*id.* ¶110), this conduct does not, without more, indicate that BTG knew Zytiga's price was inflated because of a fraudulently obtained patent. Moreover, BTG's role in developing and licensing Zytiga is not clearly related to the substance of Plaintiff's allegations.

Accordingly, I grant Defendants' motion in part to the extent of dismissing all claims against defendant BTG.

III. CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss Plaintiff's claims is **GRANTED IN PART and DENIED IN PART**. Plaintiff's claims against Defendant BTG are dismissed but the motion is otherwise denied as to the claims against the remaining Defendants.

A separate order will issue.

Dated: December 17, 2021

/s/ Kevin McNulty

Hon. Kevin McNulty
United States District Judge